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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,976	11/20/2003	Linda Thorne	850136.411	8001

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,976	THORNE ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 43-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-42* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 22, 2006, has been received and entered.

Claims 1-54 are pending. Claims 1-15 and 43-54 are withdrawn.

Claims 16-42 are examined on the merits to the extent they read on the elected subject matter.

Information Disclosure Statement

Previously, not all of the information referred to in the information disclosure statement placed in the application had been considered as no copy was provided of one non-patent literature publication. The reference listed as item BF of the information disclosure statement filed on January 10, 2005, has been received and considered. As this reference was crossed out on the signed information disclosure statement, this reference is cited in the attached Notice of References Cited (PTO-892).

Claim Objections

Claim 16 is objected to because of the following informalities: Step (k) of claim 16 recites "DNaseI" which should be replaced with "DNase I". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite since the recitation "step (a)(i)" under step (d) lacks antecedent basis. It is unclear what is "step (a)(i)." It is suggested that "step (a)(i)" be replaced with "step (i) of step (a)."

Claim 20 is rendered indefinite by the recitation "a composition suitable for use in preparing an electrophoresis medium..." Specifically, the phrase "suitable for use in" does not clearly define how the composition is used, what is the "use," or what criteria is used to determine suitability.

Applicant's arguments filed June 22, 2006, have been fully considered but they are not persuasive. Applicant asserts that the instant specification clearly describes what is a composition that is "suitable for use" in preparing an electrophoresis medium. However, it is still unclear what structural/physical characteristics would render the composition suitable for this use as the specification does not explicitly define these characteristics. Thus, claims 20-28 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-23, 25, 27-38, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole (US 6,203,680).

Cole discloses a gel comprising gellan gum, a cross-linking agent, and a size-separation modifying polymer, wherein the gel is used in an electrophoresis apparatus (claim 1). Thus, Cole teaches claims 17-21 and 27 under examination. Furthermore, the gel "further includes a buffer compound for maintaining said gel at a pH of 5 to 9" (claim 4). Therefore, Cole also anticipates instant claims 23, 29, 30, 31, 33, and 37.

The size-separation property modifying polymer of the Cole invention may be polyethylene oxide, which is a polyalkylene oxide, thus anticipating instant claims 22, 32, and 34.

The buffer used to prepare the gellan gum electrophoresis gel (column 6, lines 39-40) may be one of the buffers listed in Table 1 (column 6, line 56 through column 7, line 10), wherein one buffer used includes boric acid and EDTA (column 7, lines 7-10). See also column 8, lines 47-49. Thus, Cole anticipates instant claims 25, 35, and 40.

Since the gels are stained with ethidium bromide (column 8, lines 5-6), the reference discloses the limitations of instant claim 38. Furthermore, Cole anticipates instant claims 28 and 42 (column 11, line 65 through column 12, line 6).

Applicant's arguments filed June 22, 2006, have been fully considered but they are not persuasive. Applicant asserts that it is known in the art and disclosed in the instant specification that gellan compositions such as those taught by Cole contain significant levels of nucleic acid contaminants. However, it is respectfully pointed out that the instant specification only teaches that KELCOGEL® gellan , KELCOGEL F® gellan, and GELRITE® gellan has nucleic acid

concentrations outside the range recited in the claims (page 14, lines 11-14). Cole discloses that the gellan gum of their invention was prepared using the deionization and precipitation procedure described in Doner et al. (Carbohydrate Research. 1995. 273: 225-233, reference on Information Disclosure Statement filed January 10, 2005). See column 6, lines 24-30. Clearly, since Doner et al. teaches a purified gellan composition, with significantly diminished levels of contaminating divalent cations and phosphorus (Doner et al., page 227, second paragraph and Table 1 on page 229), the Cole composition indeed comprises gellan with significantly reduced levels of nucleic acids (phosphorus is present in the sugar phosphate backbone of nucleic acids). Therefore, Cole indeed teaches the use of gellan compositions having very low levels of nucleic acid contamination. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Nochumson et al. (US 5,143,646).

As discussed above, Cole anticipates claims 17-23, 25, 27-38, 40, and 42. However, Cole does not expressly disclose that the gel composition comprises buffer containing imidazole.

Nochumson et al. discloses an aqueous electrophoretic resolving gel composition (claim 1) which comprises a resolving gel buffer and gellan (claim 4). It is further noted that the resolving gel buffer may be imidazole (column 8, line 20).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included imidazole in the buffer used in the gellan gel composition taught by Cole. One of ordinary skill in the art would have been motivated to do this since one would have recognized the suitability of using imidazole buffers in gellan electrophoresis gels.

Applicant's arguments filed June 22, 2006, have been fully considered but they are not persuasive. As Cole anticipates claims 17-23, 25, 27-38, 40, and 42, the disclosure of imidazole as an appropriate gel buffer in Nochumson et al. is relevant. Thus, a holding of obviousness is required.

Claims 16-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole and Nochumson et al. as applied to claims 17-42 above, and further in view of Cole et al. (Applied Biochemistry and Biotechnology, 1999, 82: 57-76).

As discussed above, Cole and Nochumson et al. render claims 17-42 obvious. However, these references do not render obvious all the limitations of claim 16 since the gellan compositions taught by Cole and Nochumson et al. do not comprise of DNase.

Cole et al. teaches the same gellan gel composition as taught by Cole (page 57, abstract). In one experiment using the gellan gum gel, plasmid preparations were treated with DNase I and run on gellan gum gels (page 68, last paragraph). Thus, when these treated plasmid preparation are injected into the gellan gum gel, the gel is considered a composition comprising DNase I.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have run plasmid preparations treated with DNase I on the gels of the Cole invention. One of ordinary skill in the art would have been motivated to do this in order to have determined the separation of circular DNA in gellan gum gels, as was the goal of the experiment disclosed in the Cole et al. article. Thus, the Cole gel would have been considered a gellan gel composition comprising DNase, and would therefore render claim 16 obvious since claim 16 is a product-by process claim.

M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). For these reasons, instant claim 16 is rendered obvious.

Applicant's arguments have been fully considered but they are not persuasive. As noted above, the composition rendered obvious by the references comprises DNase, and as the claims are directed to a product-by-process, it is irrelevant whether or not DNase serves to degrade any nucleic acid that may be present in the Cole composition (if any) or to purify gellan. As pointed out above, "the patentability of a product does not depend on its method of production"

(M.P.E.P. § 2113). Further still, the motivation discussed above to include plasmid preparations treated with DNase I is not to degrade any nucleic acid in the Cole composition (if any). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Therefore, a holding of obviousness is clearly required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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